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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Robert HALLOWITZ *et al.*

Serial No.: 09/296,534

Examiner: R. Zeman

Filed: April 22, 1999

Group Art Unit: 1645

For: METHODS AND COMPOSITIONS FOR DETERMINING LATENT  
VIRAL LOAD

**RESPONSE TO FINAL REJECTION**

Commissioner for Patents  
Washington, DC 20231

Sir:

In response to the Final Office Action mailed July 18, 2000 (Paper No. 7), and further in response to the Notice of Appeal filed on December 18, 2000 (with a two-month extension of time fee being paid), please consider the following remarks.

**R E M A R K S**

A new declaration signed by the inventors will be filed in due course.

As far as the remaining rejection under 35. U.S.C. §103, it is urged that obviousness has not been established by the Patent Office. No motivation with an expectation of success has been identified. It is alleged on Page 7 of the Office Action that "Use measurement of any polyprotein that is **only** produced by the active replication of the HIV retrovirus as a measurement of viral replication would be obvious to one of skill in the art." [Emphasis added.]

In fact, no evidence has been provided by the Patent Office that gp120 is only produced in circumstances where a cell is productively infected with HIV. For instance, it is possible that integrated HIV may become transcriptionally active and produce gp120 protein, without being associated with the production of active virus. Such uncertainty is exactly why the present invention is not obvious.

The dissociation of gp120 expression from the ability to produce infectious virus is, indeed, observed when protease inhibitors are administered. Protease inhibitors block the